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10/560,441	03/30/2006	Christopher John Farrell	P1096/20006	8867

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EXAMINER	
ROBINSON, JAMES MARSHALL	
ART UNIT	PAPER NUMBER
3772	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No.	Applicant(s)	
	10/560,441	FARRELL, CHRISTOPHER JOHN	
	Examiner	Art Unit	
	James M. Robinson	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-18,20-30,40 and 42-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-18,20-30,40 and 42-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/05/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 6-18, 20-30, 40 and 42-51 are currently pending in the instant application. Claims 1, 20, 40 and 46 have been amended. Claim 19 is cancelled and new claim 51 has been added.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 6/5/2009 was filed after the mailing date of the Non-Final Office Action on 4/16/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 10, 13, 14, 17, 20, 21, 25-29, 40, & 42-45 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Kittelsen et al. (US 6,691,710).

Regarding claim 1, Kittelsen discloses a substantially rigid base member moulded (it is noted the base member is considered substantially rigid because a "substantial" component of the base member is composed of rigid material such as HDPE) as a single component and having a generally U-shaped form corresponding to

the outline of a jaw of a user, the base member (framework (86)/reverse bite plate fulcrum (106)/ traction pads (114)/encapsulating material (170)) defining at least one channel (178) within which an upper or lower row of teeth of a user can be received; a teeth engaging element (270), associated with each channel defined by a substantially rigid inner flange and substantially rigid outer flange and a web connecting the flanges (172 and 174), being made of a material (col. 6, lines 47-54) able to be user conformed or user moulded to suit the individual mouth of the user wherein the base member has a greater rigidity than the teeth engaging element; one or more compressible shock absorption channels near terminal ends of the base member which extend through a posterior outer face to a posterior inner face of the base member to substantially absorb impact shock.

Regarding claim 10, Kittelsen discloses the side open channels have a height in the range of 0.5-10mm and length lying in the range of 0.5-30mm (Col. 4, lines 44-51).

Regarding claim 13, Kittelsen discloses the teeth engaging element is made of a continuous layer of thermoplastic material that encapsulates the base member to firmly and securely mount the layer of thermoplastic material on the base member (170).

Regarding claim 14, Kittelsen discloses the continuous layer of thermoplastics material substantially covers the complete surface area of the base member (170).

Regarding claim 17, Kittelsen discloses the layer of thermoplastic material is EVA (ethylvinylacetate) which softens at a temperature of 90°C - 95°C (Col. 4, lines 64-67). The temperature at which EVA softens is an inherent property of the material.

Regarding claim 19, Kittelsen discloses the base member is formed from a rigid plastics material, which is not user conformable or mouldable in boiling water (Col. 4, lines 52-56).

Regarding claim 20, Kittelsen discloses the rigid plastics material comprises a non-thermoplastic material either alone or in combination with another plastics material (Col. 5, lines 1-5).

Regarding claim 21, Kittelsen discloses the non-thermoplastic material comprises polyethylene, polyurethane, polypropylene or santoprine (Col. 5, lines 1-5).

Regarding claim 25, Kittelsen discloses the non-thermoplastic material comprises polyethylene on its own (Col. 5, lines20-22).

Regarding claim 26, Kittelsen discloses the base member has inner and outer flanges interconnected by a web which collectively define upper and lower channels within which the upper and lower rows of teeth of the user are receivable, wherein an upper teeth engaging element is receivable in the upper channel and a lower teeth engaging element is receivable in the lower channel (28, 72, 76, 272).

Regarding claim 27, Kittelsen discloses a tongue tag on the inner flange (6) of the base member, the tongue tag being substantially centrally positioned for correctly positioning the tongue of a user during use (280), and a cut-out defined in the outer flange of the base member for allowing the appliance to adapt to varying arch sizes

(124), and breathing apertures defined in the base member for facilitating breathing by a user when wearing the appliance.

Regarding claim 28, Kittelsen discloses including locating means for correctly locating and positioning the jaws in the teeth engaging element during fitting of the oral appliance (Col. 4, lines 56-59).

Regarding claim 29, Kittelsen discloses the locating means comprise a brace arranged externally on the teeth engaging element (96).

Regarding claim 40, Kittelsen discloses a base member (76, 86) for an oral appliance for placing in a mouth of a user, having a generally U-shaped form corresponding to the outline of a jaw of a user, the base member moulded as a single component defining at least one channel (278) within which an upper or lower row of teeth of a user can be received, the base member further comprising shock absorbing means (114) taking the form of pre-designated compressible sections in order to substantially absorb impact shock.

Regarding claim 42, Kittelsen discloses being at least semi- flexible and non-thermoplastic (86).

Regarding claim 43, Kittelsen discloses the element being made of a material able to be user conformed or user molded to suit the individual mouth of the user, provided with locating means for correctly locating and positioning the jaws in the teeth engaging element (170, 270).

Regarding claim 44, Kittelsen discloses a method of fitting an oral appliance, comprising the step of immersing the oral appliance in water having a temperature sufficiently high to make the teeth engaging element moldable; inserting the appliance into a user's mouth; biting into the teeth engaging element to mould the teeth engaging element to the form of the user's jaw, and thereafter allowing the teeth engaging element to harden (Col. 7, lines 11-39).

Regarding claim 45, Kittelsen discloses a method for protecting teeth from impact shock comprising the step of inserting an oral appliance into a user's mouth before partaking of any activity whereby use of a mouthguard is desirable (Col. 7, lines 11-39).

With respect to amended limitations of claims **1, 40, 46 and 51** which recite -- a component of the substantially rigid base member is unitarily moulded from **a rigid plastics material** that is not user conformable or mouldable in boiling water --, examiner notes the base disclosed by Kittelsen comprises at least four components that cooperatively function as a base, including the framework (86), the reverse bite plate fulcrum (106), the traction pads (114), and the encapsulating material (170) which form a teeth receiving channel (178) these features do however mechanically combine to form a single unitary structure that is moulded as a single component by encapsulation material (170). As such, the component base structure is in fact moulded from a rigid plastics material, one example for instance is disclosed as high density polyethylene HDPE (col 5 ln 20-22). Therefore the end-product base is treated as a whole which will clearly be substantially rigid.

Claim Rejections - 35 USC § 103

1) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 6-8, 15, 16, & 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittelsen et al. (US 6,691,710) in view of Kittelsen et al. (US 5,152,301).

Regarding claims 6-8, Kittelsen ('710) substantially discloses the invention as claimed; see rejection to claim 1 above. However, Kittelsen ('710) fails to disclose the compressible shock absorption channels comprises open air channels defined in the base member; the air channels extend from an opening in an outer labial face of the base member, through the body therof to an opening in an inner lingual face ; the shock absorption means take the form of side open channels arranged in or near terminal ends of the generally U shaped form of the base member.

However, Kittelsen ('301) teaches a protective mouthguard for use by athletes in which the shock absorption means comprises one or more open air channels defined in the base member (102, 104; Col. 4, lines 52-56); the air channels extend from an outer face of the base member, through the body thereof to an inner face of the base member (102, 104; Col. 4, lines 52-56); the shock absorption means take the form of side open

channels arranged in or near terminal ends of the generally U shaped form of the base member (102, 104; Col. 4, lines 52-56).

It would have been obvious to one of ordinary skill in the art to modify the base member of the oral appliance of Kittelsen ('710) with the shock absorption means comprises one or more open air channels defined in the base member; the air channels extend from an outer face of the base member, through the body thereof to an inner face of the base member; the shock absorption means take the form of side open channels arranged in or near terminal ends of the generally U shaped form of the base member taught by Kittelsen ('301). Since all of the component parts are known in Kittelsen ('710) and Kittelsen ('301). Combining the known prior art elements according to known methods yielded the predictable result creating a shock absorption means in the terminal ends of the mouthpiece.

Regarding claims 15 & 16, Kittelsen ('710) discloses the layer of thermoplastic material (170), but fails to disclose thermoplastic material defines one or more openings which correspond with at least one or more of the open channels arranged in the base member; the layer of thermoplastic material extends across and covers the one or more openings which correspond with the at least one or more channels arranged in the base member and closes off the interior space defined by the channels.

However, Kittelsen ('301) teaches thermoplastic material defines one or more openings which correspond with at least one or more of the open channels arranged in the base member(104); the layer of thermoplastic material extends across and covers

the one or more openings which correspond with the at least one or more channels arranged in the base member and closes off the interior space defined by the channels (104; Col. 4, lines 52-56).

It would have been obvious to one of ordinary skill in the art to modify the base member of the oral appliance of Kittelsen ('710) with thermoplastic material defining one or more openings which correspond with at least one or more of the open channels arranged in the base member; the layer of thermoplastic material extends across and covers the one or more openings which correspond with the at least one or more channels arranged in the base member and closes off the interior space defined by the channels taught by Kittelsen ('301). Thus, it would have been obvious to one of ordinary skill in the art to integrate the covered openings which correspond to channels arranged in the base member shown in Kittelsen ('301) into the mouthpiece encapsulated by thermoplastic material shown in Kittelsen ('710) by known methods to achieve the predictable results of closing off the interior space defined by the channel to create a shock absorption means in the terminal ends of the mouthpiece.

Regarding claim 30, Kittelsen ('710) discloses the claimed invention except for the brace comprising rubber.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use rubber for the brace, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

2. Claims 9, 12, 46,47,48,49,50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittelsen et al. (US 6,691,710) in view of Kittelsen et al. (US 5,152,301) as applied to claims above, and further in view of Adell (US 4,955,393).

Regarding claim 9, Kittelsen's ('710) invention as modified by Kittelesen ('310) discloses all of the claimed limitations from above except for at least one frontal open channel arranged in a front section of the base member.

However Addell teaches a mouthguard that fully conforms to the actual impressions of the upper and lower arches (col. 1, lines 7-14) comprising at least one frontal open channel referred to as ducts (38) arranged in a front section of the base member.

Given the teachings of Addell, it would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the encapsulation material which comprises the base of Kittelsen with at least one frontal open channel arranged in a front section of the base member. Doing so would provide a shock absorbing means in the front section of the base member as well as enhance the ability of the base member to conform various sized mouths of different users.

Regarding claim 12, Kittelsen discloses the claimed invention except for the frontal open channel of the base member has a length lying in the range 2-10mm.

. It would have been an obvious matter of design choice to size the frontal open channel of the base member to a length lying in the range 2-10mm since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. Also

the invention is intended to be worn in the mouth of a human. Therefore, the dimensions of the mouthpiece are limited by the average size of the mouth of humans in order to make mouthpiece usage possible.

Regarding claim 46, Kittelsen's (710) invention as modified by Kittelsen ('310) discloses all of the claimed limitations from above except for a front opening defined in the outer flange of the front region.

However Addell teaches a front opening defined in the outer flange of the front region.

Given the teachings of Addell, it would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the mouthpiece of Kittelsen with a front opening defined in the outer flange of the front region.

Doing so would provide a shock absorbing means in the front section of the base member in addition to shock absorbing means at the terminal ends by the molars of the user. The front opening is simply a duplication and re-positioning of the side channels to provide shock absorbing capabilities at the front of the base member.

Regarding claim 47, Kittelsen ('710) discloses the guard defines only an upper said channel to fit over the upper arch of the use (278).

Regarding claim 48, Kittelsen ('710) discloses the outer flange includes a downward extension or skirt that extends down from the web in a direction away from the upper channel and the side openings are defined in the outer flange in the flange or skirt below the web (72, 172).

Regarding claim 49 & 50, Kittelsen's (710) invention as modified by Kittelesen

('310) discloses all of the claimed limitations from above except for the front opening is also defined in the outer flange below the web.

However Addell teaches the front opening is also defined in the outer flange below the web.

Given the teachings of Addell, it would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the mouthpiece of Kittelsen with the front opening is defined in the outer flange below the web.

Doing so would provide a shock absorbing means in the front section of the base member in addition to shock absorbing means at the terminal ends by the molars of the user. The front opening is simply a duplication and re-positioning of the side channels to provide shock absorbing capabilities at the front of the base member.

3. Claims 11, 18, 22-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Kittelsen et al. (US 6,691,710).

Regarding claim 11, Kittelsen discloses the claimed invention except for base member have a length lying in the range 10-20mm.

It would have been an obvious matter of design choice to size the base member to a length lying in the range of 10-20mm since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. Also the invention is intended to be worn in the mouth of a human. Therefore, the dimensions of the mouthpiece are limited

by the average size of the mouth of humans in order to make mouthpiece usage possible.

Regarding claim 18, Kittelsen discloses the layer of thermoplastic material but fails to disclose the teeth engaging elements has a thickness of 1mm-3mm.

It would have been an obvious matter of design choice to size the thermoplastic layer to a thickness of 1mm-3mm since such a modification would involved utilization of a reasonably thick coating layer. This design choice is generally recognized as being within the level of ordinary skill in the art. Also this layer thickness allows the thermoplastic layer to engage the teeth of the user.

Regarding claims 22-24, Kittelsen discloses the claimed invention except for the other plastics material is a thermoplastic material and the thermoplastic material is 10% or less by weight of the base member; the base member comprises 3- 8% by weight of thermoplastic material that is EVA and the balance is polyethylene; the base member comprises 4- 6% by weight of thermoplastic material that is EVA and the balance is polyethylene. In view of Kittelsen (Col. 5 line 65—Col. 6 line 54) it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize these mixture ration, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Response to Arguments

1. Applicant's arguments filed 10/16/2009 have been fully considered but they are not persuasive. Examiner maintains the base disclosed by Kittelsen comprises at least four components that cooperatively function as a base, including the framework (86), the reverse bite plate fulcrum (106), the traction pads (114), and the encapsulating material (170) which form a teeth receiving channel (178) these features do however mechanically combine to form a single unitary structure that is moulded as a single component by encapsulation material (170). \

In response to applicants stated position that Kittelsen does not disclose a base member having compressible channels that absorb shock in combination with the base elements stated above examiner respectfully asserts that the "base member" comprises

index openings (94) in the base element framework which is composed of a flexible material (col. 4, lines 52-56) that function to absorb impact shock. Although the index openings do also allow the knob projections (116) of the traction pads (114) to pass through aperture (110) in the bite plate framework it is the examiners position that in use, when a user "bites down" on the oral appliance the flexible material of the openings (94) are capable of absorbing shock transmitted from the teeth of the user to the openings (94) of the base.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., each part of the base is formed from a rigid plastic material that is not user conformable or mouldable) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With respect to applicant's position on page 11 of Remarks which cites a recitation from the Kittelsen reference stating "there are no rigid lingual or buccal walls in the appliance 70" examiner respectfully disagrees with applicant's reasoning. It is clear from a careful reading of Kittelsen that the section cited by applicant is in reference to the method or directions to fit the oral appliance to the user's mouth. Column 7, lines 11-34 states:

> ***To fit the mouthguard 70 to the user's mouth, the mouthguard 70 is placed in hot water*** *at about 211.degree. F. (i.e., water that has been brought to a boil and taken off the heat) for about 15 seconds. The mouthguard is then removed from the hot water, and it will be very soft,*

> *but the framework 86 will hold the mouthguards general shape. Excess water is allowed to drain off the mouthguard 70 by holding it with a spoon or the like.*
>
> ***Next, the wearer carefully places the mouthguard in the mouth*** *so that the interior portion of the appliance 70 touches or covers the eye teeth (the third set of teeth from the front) and extends backwardly toward the molars. Next, the wearer bites down firmly on the appliance. With a strong sucking motion, the wearer draws out all air and water from the mouthguard 70. The projections or knobs 116 of the traction pads 114 will index to the cusp 26 of the molars 22.*
>
> ***The wearer then*** *uses his hands, fingers and tongue to press the outside of the cheeks and lingual wall 72 against the appliance 70 as the* ***softenable material 170 oozes inwardly and outwardly to custom form the lingual and buccal walls*** *172 and 174 respectively.* ***Because there are no rigid lingual or buccal walls in the appliance 70, the mouthguard 70 will fit any width of molar 22 or mouth.***

Further it is noted that applicant's claim actually recites "substantially rigid". It is noted that the qualifier "substantially" is a qualitative term that is not precise. During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." The Federal Circuit's en banc decision in Phillips v. AWH Corp., 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard. The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. In re Cortright, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999). As such, the flanges defining the channel of the Kittelsen device, when in use (i.e., after being fit and cooled to standard room temperature, no longer being pulled from boiling water) are in fact "substantially rigid". Regardless of one's interpretation of substantially rigid, examiner maintains that this limitation can in no way be considered as absolutely inflexible. Since the channel

flanges of Kittelsen are intended to fit to a user's dentition, thus holding the oral appliance in place, the flanges must be at least substantially rigid.

Conclusion

2) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Robinson whose telephone number is (571) 270-3867. The examiner can normally be reached on Mon-Fri 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James M. Robinson/

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772